

REMARKS

Claims 1-4 remain pending. Reconsideration is respectfully requested.

Claim Rejections

Claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as being anticipated by Russell, U.S. Patent No. 3,866,601 (“Russell”).

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Russell in view of Baier U.S. Patent No. 4,266,999 (“Baier”).

These rejections are respectfully traversed.

35 U.S.C. § 102(b) Rejections

Claim 1

Russell does not disclose or suggest each of the features and relationships recited in claim 1. Claim 1 is directed to an infection protection device for an endoexo-implantation. In contrast Russell is directed to a speculum, which operates in an unsterile environment. Nowhere does Russell show that its device penetrates the skin or ever extends into a sterile area of the internal body. Rather, the objective of the flexible sheath of Russell is to facilitate the introduction of devices like a speculum and reduce the friction between the device and body cavity walls.

The Action asserts that Figures 5-7 of Russell demonstrate that the moving-out of the protective membrane is automatically performed from the inside of the body. Applicants respectfully disagree. The operation of Russell’s device is performed **manually** by a doctor as shown in Figure 2. Further, Russell’s device operates in an opposite manner as to that recited in

claim 1. For example, as described in Column 2, lines 19-25, Russell's tube (10) must be **pushed** (not pulled) in an **inward direction** to move or feed the sheath (22) into the body passage. Nowhere does Russell disclose or suggest that its flexible sheath is capable of being (as recited in claim 1) rolled out or unfolded in the inside of the body **when moved out by means of a pulling device (5) on the outside**.

Thus, Russell does not disclose each and every element of the claimed invention arranged in the manner recited in the claims, as is required to sustain the rejection. Hence, Applicants' claim 1 patentably distinguishes over Russell. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(b) rejection has been overcome. It follows that claims 2-4 which depend from claim 1 are likewise allowable.

Claim 2

As discussed previously with respect to claim 1, Russell discloses manual operation of its device (See Figure 2). Nowhere does Russell disclose or suggest its device operates automatically. Further nowhere does Russell disclose or suggest that its device is capable of the recited feature of "moving out of the tube-shaped protective membrane (2) being performed automatically from the inside of the body."

As nothing in the applied art discloses or suggests these recited features and relationships, it is respectfully submitted that the rejection of claim 2 should be withdrawn.

35 U.S.C. § 103(a) Rejections

Applicants respectfully submit that the combination of Russell and Baier also does not disclose or suggest the recited features discussed previously with respect to claims 1 and 2. For example, nowhere do Russell and Baier disclose or suggest the recited features in claims 1 and 2 of:

- the tube-shaped protective membrane (2) being folded or rolled up, attached permanently and hermetically with its end (3) to the endoexo-implantation (1) **and is rolled out or unfolded in the inside of the body when moved out by means of a pulling device (5) on the outside in the form of a roll-membrane.**

and/or

- the moving out of the tube-shaped protective membrane (2) being performed **automatically from the inside of the body**

Thus, the Office has not established *prima facie* obviousness with respect to claims 3-4.

In addition, a person of ordinary skill in the art at the time of the invention would have no apparent reason to modify the applied art in a manner which includes all of the features and relationships recited in the pending claims. Russell and Baier an non-analogous art. There is no apparent reason to use the alleged features of Baier in Russell's speculum.

Further, a person of ordinary skill in the art at the time of the invention would not regard claims 1-4 as being obvious in view of the applied art for any of the following rationales: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; use of known technique to improve similar devices (methods, or products) in the same way; applying a known

technique to a known device (method, or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. In conclusion, it was not known nor would it have been obvious to a person having ordinary skill in the art having full view of the applied art, to have produced the claimed features and relationships recited in claims 1-4. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection of claims 3-4 should be withdrawn

The Applicable Legal Standards

In order to present a valid rejection based on obviousness, it is first necessary for the Office to make a *prima facie* showing of obviousness. *Prima facie* obviousness requires a showing that each of the recited features and relationships in the claims was known in the prior art. If the Office fails to establish a *prima facie* case of obviousness, the Applicant is under no obligation to submit evidence of non obviousness. MPEP § 2142.

Even in cases where the Office has made a *prima facie* showing of obviousness, a rejection cannot be properly made unless there is a requisite showing that it would be obvious to one having ordinary skill in the art to combine the features and relationships to produce the invention as claimed. In accordance with the dictates of the United States Supreme Court in *KSR*

Int'l. Co. v. Teleflex, Inc., 127 S.Ct. 1727, 82 USPQ 2d 1385 (2007) the determination as to whether there is a reason to combine features of prior art references must be evaluated through an analysis of the factors recited in *Graham v. John Deere*, 383 U.S.1, 148 USPQ 459 (1966). The factual inquiries that must be made under *Graham* include:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art;
- (d) evaluating evidence of secondary considerations.

Thus, in accordance with the requirements of *Graham*, it is mandatory that before a claim can be rejected on the basis of obviousness, the Office is required to make a factual determination and resolve the level of ordinary skill in the pertinent art at the time that the invention was made. MPEP § 2141(2)(C). It is respectfully submitted that the Action from which this appeal is taken does not meet these burdens.

Conclusion

Each of Applicants' pending claims specifically recites features and relationships that are neither disclosed nor suggested in any of the applied art. Furthermore, the applied art is devoid of any apparent reason or any other rational such as a teaching, suggestion, or motivation for combining features of the applied art so as to produce Applicants' invention. Allowance of all of Applicants' pending claims is therefore respectfully requested.

The undersigned will be happy to discuss any aspect of the Application by telephone at the Examiner's convenience.

Respectfully submitted,

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